REMARKS

By this paper, claims 14, 24 and 34 have been amended. Claims 14-38 remain pending of which claims 29-33 have been withdrawn.

In the Office action dated August 6, 2003, the Examiner objected to claims 14 to 18 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. In particular, the Examiner considers the expression "cataract-like disorders" in claim 14 as indefinite. Although previously so amended in a paper dated October 19, 1998, to eliminate any confusion which may have resulted from our February 5, 2003 submission, claim 14 has again been amended by replacing the phrase "cataract-like disorders" with "after-cataract formation." As such, it is believed that claims 14-18 now satisfy the requirements of 35 U.S.C. § 112, second paragraph.

The Examiner has also objected to claims 14 to 28 and 34 to 38 as failing to comply with the written description requirement. The Examiner has stated that the specification shows the treatment or inhibition of cataract induced by TGFβ by using an inhibitor of TGFβ. However, the Examiner also has stated that there is no support for the prevention of cataract in general. To address the Examiner's concerns, claims 14 and 34 have been amended to refer to preventing or controlling "TGFβ-induced cataract." Thus, the claims now define the invention in a manner that corresponds to the subject matter the Examiner has stated is described in the specification. Support for the recitation of "TGFβ-induced cataract" is provided throughout the specification. For example, page 1, lines 3 to 7 states that the invention relates to preventing or controlling pathological changes which occur in association with cataract formation in a mammalian eye by reducing the amount of or inhibiting the action of TGFβ. See also page 3, lines 7 to 12. Example 1 provides experimental evidence that TGFβ induces changes that typically occur in certain forms of cataract. See also Examples 2 to 4. Accordingly, we submit that the

specification does indeed describe the invention in clear terms as to enable a person skilled in the art to make and use the invention. The specification also provides evidence of the role of TGFβ in the formation of cataract and after-cataract. Moreover, the specification describes the use of inhibitors of TGFβ to prevent or control these changes. In fact, examples 2, 3 and 4 provide evidence of the inhibition of these changes, demonstrating that the inventors were in possession of the invention defined by the amended claims. Therefore, it is believed that the pending claims also satisfy 35 U.S.C. § 112, first paragraph.

It is to be noted that the Examiner has indicated that the § 112, first paragraph rejection applies to each of claims 14 to 28 and 34 to 38. However, we note that in the previous Office action, the Examiner had indicated that claims 24 to 28 were allowable. Accordingly, we query whether the Examiner's objection to these claims was in error. "After-cataract" is a well-characterized clinical condition that follows cataract surgery. It was believed to have been understood that there is no ambiguity concerning the condition described by that term. The specification clearly describes this condition and the prevention and control of this condition by administering an inhibitor of TGFβ (see for example, page 1 lines 7 to 9 and 16 to 24, page 2 lines 17 to 22, and page 4 lines 2 to 7). Therefore, it is respectfully requested that the rejection of claims 24 to 28 be withdrawn.

Furthermore, in the outstanding Office action, the Examiner has rejected claims 14 to 23 and 34 to 38 on the basis that they lack novelty in light of WO 92/17206. We note that this rejection does not apply to claims 24 to 28. WO 92/17206 describes a composition and method for preventing scar tissue formation. The Examiner appears to consider that the method disclosed in the cited document would inherently prevent cataract formation, and thus the cited document anticipates the present invention. The cited document notes that the described method

of treatment must be applied at an early stage of wound healing, typically once or only a few times within a period of about 3 to 14 days after the initial occurrence of the wound (see pages 14 and 15). The time of occurrence of such a wound and the application of the treatment method described in the cited document may occur at any time, and the timing of this event is not in any way related to a patient's need for the treatment or prevention of TGFβ-induced cataract or after-cataract formation. The patient having the wound may not have cataract or after-cataract and may not be susceptible to cataract or after-cataract formation. Accordingly, the treatment method described in the cited document would not inherently be effective in preventing TGFβ-induced cataract or after-cataract formation in the patient. The cited document does not disclose or suggest that the treatment method described in the cited document would be effective in preventing or controlling TGFβ-induced cataract or after-cataract formation.

Nevertheless, to address the Examiner's concerns, we have amended claims 14 and 34 to state that the subject is "in need of such prevention or control." There is no disclosure or suggestion in WO 92/17206 of an recognition that administration of an inhibitor of TGFβ to prevent or control TGFβ-induced cataract or after-cataract formation. There is no disclosure or suggestion that any patient referred to in the cited document is in need of such prevention or control. Accordingly, it is respectfully submitted that amended claims 14 to 23 and 34 to 38 are clearly novel over the cited document.

CONCLUSION

Applicants have attempted to respond to each and every rejection set forth in the outstanding Office Action. In view of the above amendments and remarks, Applicants respectfully request that the application be reconsidered, the claims allowed and the application passed to issue.

Respectfully submitted,

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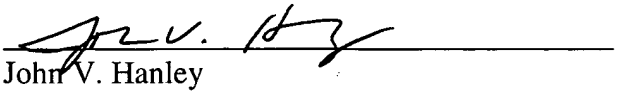
By: 

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